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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/605,903 | 11/05/2003 | Shankara Bonthu Reddy | 138162 | 2902 |

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| EXAMINER |
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SOLANKI, PARIKHA

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| ART UNIT | PAPER NUMBER |
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3737

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/605,903 | Applicant(s) REDDY ET AL. | |
| | Examiner Parikha Solanki | Art Unit 3737 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/5/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :11/5/03, 11/26/03, 9/13/04, 12/20/04, 3/17/06, 7/10/06, 8/16/06, 10/26/06.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements (IDS) submitted on 11/26/03, 9/13/04, 12/20/04, 3/17/06, 7/10/06, 8/16/06, 10/26/06 were filed after the mailing date of the application on 11/5/03. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.
2. The information disclosure statement filed on 12/20/04 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Specification

3. The disclosure is objected to because of the following informalities: paragraph [0006] of the specification, line 9, contains a typographical error. The word "Tebesian" should be corrected to read "Thebesian." Appropriate correction is required.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:
Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
5. Claims 1-39 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The PTO guidelines as set forth in the O.G. 11/22/2005 provide a two-pronged test for determining whether a method or apparatus meet the requirements of statutory subject matter. If the invention does not result in a physical transformation of an object, then the claims must clearly provide a useful, concrete and tangible result such as diagnosis of disease or generation of a report. The methods described by claims 1-39 do not result in a physical transformation of an object, and they do not provide a useful, concrete and tangible result. The step of "identifying at least one suitable region on the left ventricle for epicardial lead placement," recited in independent claims 10 and 22, is not sufficiently descriptive so as to provide the method with a useful, concrete and tangible result. Examiner

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suggests that independent claims 1, 10 and 22 should be modified to include a step describing the actual placement of an epicardial lead based on the quantification analysis and 3D model, or a similar modification thereof which provides a useful, concrete and tangible result, so as to remedy the current statutory deficiencies of rejected claims 1-39.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-8 and 40-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Gerard et al (Efficient Model-Based Quantification of Left Ventricular Function in 3-D Echocardiography. *IEEE Transactions on Medical Imaging*. 21(9): pp. 1059-68. September 2002.).

Gerard (2002) provides a system and method for quantifying left ventricular (LV) function using 3-D echocardiography (Abstract, p. 1059 col. 2). Gerard (2002) includes the steps of acquiring cardiac image data, determining a 4D motion model, equivalent to a movement profile, from the image data, and visually displaying the movement profile via a 3D model (Figs. 1, 2, 4). Gerard (2002) further discloses identifying the profiles of contraction parameters for each of a plurality of designated regions (p. 1063 col. 1, Figs. 6 and 7). The displacement profile of Gerard (2002) shows a region of maximum displacement at a specified point in time, and it is disclosed that the image acquisition may be EKG-gated (Fig. 6, p. 1065 col. 2 Section A). The contraction curve of Gerard (2002) shows which region is last to achieve a state of maximum contraction based on displacement versus time information (Fig. 6). The contraction ratio and motion model disclosed by Gerard (2002) inherently provide velocity versus time information for each region over a cardiac cycle to identify which region is last to achieve maximum velocity (Figs. 5 & 6, p. 1063 col. 1 Section C).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gerard (2002). Gerard teaches a method of quantifying LV wall motion deformities as described above. Gerard (2002) does not explicitly disclose the application of such a method to quantifying right ventricular (RV) wall motion. Examiner hereby takes official notice that quantifying RV function in accordance with the method of Gerard (2002) would have been obvious to one of ordinary skill in the art at the time of invention. It is well-known in the art that mechanical dyssynchrony as associated with heart failure involves dyssynchrony between the contraction of both ventricles, and in the case of LBBB it is routine to observe RV contraction relative to LV contraction in order to assess the degree of bundle branch block, and to investigate whether there is any additional bundle branch block on the right side of the heart. Furthermore, inconsistencies in septal wall motion are commonly associated with mechanical LV dysfunction. Since septal motion affects both RV and LV contraction, it would have been obvious to one of ordinary skill in the art to quantitatively assess the effects of septal wall motion deformities on RV function in patients presenting with LV mechanical dysfunction via the method of Gerard (2002).

10. Claims 10-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerard (2002) in view of Wahle et al (3D Heart Vessel Reconstruction from Biplane Angiograms. *IEEE Computer Graphics and Applications*. 16(1): pp. 65-73. January 1996).

Regarding claims 10 and 20, Gerard (2002) discloses all features of the present invention, with the exception of visualizing one or more coronary vessels on the generated 3D model. Wahle et al (1996) disclose a method of visualizing coronary vessels in 3D for the purpose of planning subsequent treatment (Abstract). The method of Wahle (1996) includes steps for quantifying dimensions of the imaged blood vessels. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Gerard (2002) to include the coronary vessel visualization and quantification method of Wahle (1996), in order to identify the placement of the coronary vessels to provide a more comprehensive anatomical model for planning treatment.

Also regarding claim 10, Gerard (2002) also does not explicitly disclose identifying at least one suitable region on the left ventricle wall for epicardial lead placement. It is known in

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the art that it is desirable to apply left ventricular pacing therapy to the area on the LV that is last to contract during systole in order to optimize cardiac resynchronization. Therefore, identification of the point of last contraction is equivalent to identification of a suitable region for lead placement. Gerard (2002) discloses identifying the point of last contraction as described above, and therefore this limitation is considered inherent to the method of Gerard (2002). It would have been obvious to one of ordinary skill in the art to use the method of Gerard (2002), modified by Wahle (1996) to identify potential regions for epicardial lead placement.

Regarding claim 11, Gerard (2002) does not explicitly discuss identification of necrosed tissue. However, it is known in the art that, during echocardiographic imaging, necrosed tissue is identified as that tissue which exhibits hypokinetic or akinetic motion during the cardiac cycle. Gerard (2002) teaches the use of echocardiography for generating the 3D model of the heart. Therefore, one of ordinary skill in the art at the time of invention would consider it obvious that the method of Gerard (2002), as modified by Wahle (1996), includes the identification of necrosed tissue. One of ordinary skill in the art at the time of invention would further consider it obvious to avoid the identified ischemic regions when considering potential sites for pacing lead placement, as ischemic tissue is well-known to have poor conductive capacity.

Regarding claim 12, it is known in the art that epicardial leads must be attached to the heart via a screw or suture mechanism. It is also known in the art that actively fixing an epicardial pacing lead directly to a coronary vessel or myocardium is dangerous and harmful to the patient. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to eliminate the visualized blood vessel, along with its surrounding myocardium, as suitable regions for epicardial lead placement.

Regarding claims 13-19, the limitations recited in these claims are rejected as being obvious over the method of Gerard (2002) modified by Wahle (1996), on the same grounds of rejection applied to claims 2-8 above.

Regarding claim 21, Gerard (2002) and Wahle (1996) teach all limitations of the present invention as described above, with the exception of quantifying right ventricular function. Claim 21 is considered obvious over the method of Gerard (2002), modified in view of Wahle (1996), on the same grounds of rejection applied to claim 9 in paragraph 6 of this Office Action.

11. Claims 22-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerard (2002) in view of Wahle et al (1996), further in view of Lattouf (US PG Pubs. No.

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2003/0120264). The system and method of Gerard (2002), when combined with Wahle (1996), includes components and steps for obtaining cardiac image data, determining a movement profile from the image data, visually displaying the movement profile by generating a 3D model therefrom and visualizing coronary vessels on the 3D model as applied to claim 10 above. The steps disclosed by Wahle (1996) display the major coronary blood vessels, which, by definition, include the coronary sinus and its major branches. Gerard (2002) teaches the use of performing the imaging method with a real-time 3-D system from Philips Medical Systems, which inherently performs the steps of registering and visualizing saved views of the 3D model, and which is equivalent to the interventional system claimed in the instant application (p. 1059, col. 1).

In the general state of the art at the time of invention, it was known that the coronary sinus constitutes a left ventricle anatomical landmark. Since Wahle (1996) teaches displaying the coronary vessels, which include the coronary sinus, the combined method of Gerard (2002) and Wahle (1996) includes the step of identifying a left ventricle anatomical landmark as claimed in the instant application.

Regarding claims 23-31, 37 and 38, these steps and limitations are taught in the method of Gerard (2002) as modified by Wahle (1996), as discussed for claims 11-21 above.

Regarding claims 32-34, Gerard (2002) teaches generating short axis images of the LV and thoracic wall, as well as acquiring the image data in an ECG-gated manner (Figs. 5, 11 & 14, p. p. 1065 col. 2).

Regarding claims 35 and 36, Gerard (2002) provides a method of segmenting data acquired through ultrasound and MR imaging using a 3D protocol and short axis protocols (Abstract, Fig. 1, p. 1060 col. 2 – p.1062 col. 1, p. 1063 col. 1).

Regarding claim 39, the method of Gerard (2002) includes generating a 3D image model as applied to claim 10 above, the generated image being equivalent to a report for diagnosis and interventional planning as claimed in the instant application.

Gerard (2002) and Wahle (1996) do not explicitly disclose the steps of identifying a suitable region on the left ventricle wall for epicardial lead placement, identifying coronary sinus branches closest to the suitable region and displaying the coronary sinus branches on the 3D model, or identifying a minimally invasive route for epicardial lead placement.

As previously discussed with regards to claims 10 and 12, it would have been obvious to one of ordinary skill in the art to perform the method of Gerard (2002) and Wahle (1996) to identify a region suitable for epicardial lead placement by avoiding regions including coronary

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vessels, so as to avoid harming the patient, and by identifying the point of last contraction on the LV in order to optimize the patient's response to cardiac resynchronization therapy.

Lattouf ('264) teaches a system and method for implanting an epicardial lead via mini-thoracotomy, which employs delivery of the lead via a minimally invasive route as claimed in the instant application (Abstract, paragraph 0017). Lattouf ('264) discloses gaining access to the implant site via an opening in the intercostal space between the patient's ribs. At the time of invention, it would have been obvious to one of ordinary skill in the art to combine the system and method of Lattouf ('264) with that of Gerard (2002), previously modified by Wahle (1996), in order to identify the specific intercostal space closest to the desired epicardial lead implant location, so that the minimally invasive route is as short as possible to ease delivery of the lead through the patient's body, and to avoid having to perform an open-chest procedure that would present significant additional trauma and risk of infection to the patient.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Derumeaux et al (Doppler Tissue Imaging Quantitates Regional Wall Motion During Myocardial Ischemia and Reperfusion. *Circulation*. 97: pp. 1970-1977. 1998) disclose a related method of quantifying regional myocardial dysfunction as induced by ischemia, including methods of characterizing myocardial wall velocities using tissue Doppler imaging techniques. Mair et al (Epicardial Lead Implantation Techniques for Biventricular Pacing via Left Lateral Mini-Thoracotomy, Video-Assisted Thoracoscopy, and Robotic Approach. *The Heart Surgery Forum*. Volume 6(5): pp. 412-417. August 2003) disclose the state of the art techniques for identifying suitable regions for epicardial LV lead placement. Murashita et al (US Patent No. 5,515,849), Vesely (US Patent No. 6,246,898) and Cline (US Patent No. 6,058,218) teach related methods and systems for imaging the heart and coronary vessels.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parikha Solanki whose telephone number is 571.272.3248. The examiner can normally be reached on M-F, 8 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571.272.4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Parikha Solanki
Examiner – Art Unit 3737



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